

Review Date: _____

Informed Consent Checklist for Protocol # _____

CDC holds a Multiple Project Assurance with the Office for Protection from Research Risks (OPRR), NIH, whereby CDC agrees to abide by the requirements of Title 45 Code of Federal Regulations for the Protection of Human Subjects (45 CFR 46).

Section 116 (§46.116) of the federal regulations gives the general requirements for informed consent. The section reads, in part, "...no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject..."

The purpose of this checklist is to aid you in your evaluation of the informed consent documents accompanying each protocol to assure that those required elements are included. Please use the blocks to make notes or simply check that the basic requirement has been satisfactorily addressed.

All consent document must address the following three principles:

| Requirement | 45 CFR 46.116 | Consent form |
|----------------------|--|--|
| <i>Voluntariness</i> | A. "An investigator shall seek...consent only under circumstances that provide the prospective subject...sufficient opportunity to consider whether or not to participate..." | |
| | B. "...and minimize the possibility of coercion or undue influence." | |
| <i>Comprehension</i> | "The information...given to the subject...shall be in language understandable to the subject..." The reading grade level and method (SMOG, Fry, Flesch-Kincaid) used to determine the reading grade level must be specified. | Grade level: _____ SMOG: _____ Fry: _____ Flesch-Kincaid: _____ |
| <i>Coercion</i> | No informed consent... may include any exculpatory language through which the subject...is made to waive...any of the subject's legal rights, or releases the investigator, the sponsor or the institution ...from liability for negligence. | |

Minimal Risk

The Federal Regulations divide research into that which is minimal or not greater than minimal risk to the participant and that which is greater than minimal risk. The definition of minimal risk given in §46.102(I) reads as follows:

"Minimal risk means that the **probability** and **magnitude** of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

Level of Risk for this protocol (please insert "minimal" or "greater than minimal"):

Required Elements of Informed Consent

The Federal Regulations at §46.116 describes eight elements required in each consent document. Element number six is only required if the research is determined to be greater than minimal risk. This section also lists an additional six elements that “When appropriate...shall also be provided to each subject.”

Please use the following determination key when evaluating each element:

- Y** = appropriately included in the consent form
N/A = element not required for this study (IRB must waive and document)
M = element missing (the consent form must be revised to include this element or the requirement must be waived by the IRB)
I = incomplete or problematic

| Element | 45 CFR 46.116(a) | Consent form |
|----------|---|--------------|
| 1 | A. a statement that the study involves research | |
| | B. an explanation of the purposes of the research | |
| | C. the expected duration of the subject’s participation | |
| | D. a description of the procedures to be followed | |
| | E. identification of any procedures which are experimental | |
| 2 | a description of any reasonably foreseeable risks or discomforts to the subject | |
| 3 | a description of any benefits to the subject or to others which may reasonably be expected from the research | |
| 4 | a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject | |
| 5 | a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained | |
| 6 | A. an explanation as to whether any compensation is available if injury occurs | |
| | B. an explanation as to whether any medical treatments are available if injury occurs, and, if so | |
| | C. what they consist of or where further information may be obtained | |
| 7 | A. an explanation of whom to contact for answers to pertinent questions about the research | |
| | B. an explanation of whom to contact for answers to pertinent questions about the research subjects’ rights | |
| | C. whom to contact in the event of a research-related injury to the subject | |

| Element | 45 CFR 46.116(a) | Consent form |
|---|---|--------------|
| 8 | A. a statement that participation is voluntary | |
| | B. refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled | |
| | C. the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled | |
| Additional elements (45 CFR 46.116(b) of informed consent (when appropriate, one or more of the following elements of information shall also be provided to each subject): | | |
| 1 | a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable | |
| 2 | anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent | |
| 3 | any additional costs to the subject that may result from participation in the research | |
| 4 | A. the consequences of a subject's decision to withdraw from the research | |
| | B. procedures for orderly termination of participation by the subject | |
| 5 | a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject | |
| 6 | the approximated number of subjects involved in the study | |